What we claim is:

1. A recombinant DNA molecule comprising a DNA sequence that codes for the external domain of the c-erbB-2 protein (gp75) or for one or more portions of said gp75, wherein said DNA sequence is operatively linked to an expression control sequence in said DNA molecule.

2. A recombinant DNA molecule according to Claim 1 which codes for one or more portions of said gp75 wherein said portion or portions is or are serologically active, antigenic and/or immunogenic.

3. A unicellular host which is either prokaryotic or eukaryotic transformed with the recombinant DNA molecule of Claim 1.

4. A unicellular host acording to Claim 3 which is eukaryotic.

5. A unicellular host according to Claim 3 wherein the recombinant DNA molecule is a recombinant cloning vehicle comprising a first and a second restriction endonuclease recognition site, said DNA sequence being inserted between said first and second restriction sites.

6. A unicellular host according to Claim 3 which is selected from the group consisting of strains of E. coli, Pseudomonas, Bacillus, yeast, other fungi, and animal, insect, and plant cells in culture.

7. A unicellular host according to Claim 4 which is selected from the group consisting of yeast and mammalian cells in culture.

8. A unicellular host according to Claim 7 which is a mammalian cell selected from the group consisting of monkey cells and Chinese Hamster Ovary (CHO) cells in culture.

9. A unicellular host according to Claim 8 wherein the monkey cells are from the cell line COS7 and the CHO cells are from the cell line CHO-(dxb11).

10. A recombinant DNA molecule according to Claim 1 which is plasmid pFRSV-c-erbB-2 sec.

11. A purified and isolated DNA molecule for use in securing expression in a prokaryotic or eukaryotic host cell of a protein or polypeptide product having at least part of the amino acid sequence of gp75, said DNA selected from:

(a) DNA molecules encoding for gp75 or fragments thereof;

(b) DNA molecules which hybridize to the DNA sequence of a) or fragments thereof; and

(c) DNA molecules which, but for the degeneracy of the genetic code, would hybridize to the DNA molecules defined in a) and b).

12. A purified and isolated DNA molecule according to Claim 11 wherein the host cell is eukaryotic.

13. Recombinant gp75 proteins and polypeptides.

14. Recombinant gp75 proteins and polypeptides according to Claim 13 which are glycosylated.

15. Recombinant gp75 proteins and polypeptides according to Claim 14 which are serologically active, immunogenic and/or antigenic.

16. Substantially pure, gp75 protein and any polypeptide portion thereof.

17. Antibodies, both monoclonal and polyclonal, to the recombinant gp75 proteins and polypeptides of Claim 14.

18. A method of treating mammals for neoplastic disease by administering the antibodies of Claim 17.

19. A method for producing gp75 proteins and/or polypeptides comprising the steps of:

a) transforming a unicellular host with a recombinant DNA molecule of Claim 1;

b) culturing said unicellular host so that said gp75 proteins and/or polypeptides are expressed; and

c) extracting and isolating said gp75 proteins and/or polypeptides.

20. A method of testing mammalian body fluids for the presence of gp75 which comprises contacting a composition containing antibodies to gp75 proteins and/or polypeptides, with a sample of a mammalian body fluid and determining whether said antibodies bind to a protein in said sample.

21. A method according to Claim 20 wherein the mammalian body fluids are human body fluids selected from the group consisting of serum, semen, plasma, breast exudate, urine, saliva, and cerebrospinal fluid.

22. A method according to Claim 21 wherein the human body fluids are selected from the group consisting of serum, plasma, and semen.

23. A method according to Claim 22 wherein the human body fluid is serum or plasma.

24. A diagnostic method for neoplastic disease associated with c-erbB-2 amplification employing an immunoassay to detect gp75 in human body fluids.

25. A method according to Claim 24 wherein the neoplastic disease is a tumor of an organ having a secretory function.

26. A method according to Claim 24 wherein the neoplastic disease is a tumor of epithelial origin.

27. A method according to Claim 24 wherein the neoplastic disease is associated with a tumor or tumors of tissues from the group consisting of salivary glands, thyroid gland, breast, ovary, prostate gland, brain, pancreas, gastrointestinal tract, urinary tract, and liver.

28. A method according to Claim 27 wherein tissues are from the group consisting of breast, ovary and prostate.

29. A method according to Claim 24 wherein the neoplastic disease is a breast adenocarcinoma and/or an ovarian adenocarcinoma.

30. A method according to Claim 20 which comprises the use of a sandwich assay wherein one antibody is to intact gp75 external domain on a human cancer cell line and the other antibody is to intact gp75 external domain on $NIH3T3_t$ cell line.

31. A method according to Claim 20 which comprises the use of a sandwich assay, ELISA assay or equivalent assay which can be unamplified or amplified using avidin/biotin technology.

32. A method for the determination of the presence of gp75 in mammalian body fluids wherein antibodies according to Claim 17 are employed.

33. A method according to Claim 20 wherein antigen in the sample of the human body fluid competes with a labeled gp75 or protein or polypeptide thereof for the binding to antibodies recognizing gp75.

34. A method according to Claim 33 wherein a sandwich method is performed using antibodies to the gp75 proteins and/or polypeptides.

35. A test kit for assaying gp75 in human body fluids which comprises:

a) antibodies to gp75 proteins and/or polypeptides and/or antibodies to whole cells expressing c-erbB-2; and

b) a detection means.

36. A test kit for assaying gp75 proteins and/or polypeptides in human body fluids which comprises:

a) gp75 proteins and/or polypeptides and/or anti-idiotype antibodies to gp75 proteins and/or polypeptides; and

b) a detection means.

37. A vaccine comprising an immunogenic amount of one or more substantially pure, gp75 proteins and/or polypeptides dispersed in a physiologically acceptable, nontoxic vehicle, which amount is effective to immunize a human against neoplastic disease associated with amplification of c-erbB-2.

38. A vaccine comprising an immunogenic amount of cell membranes which express gp75 on their surface dispersed in a physiologically acceptable, nontoxic vehicle, which amount is

effective to immunize a human against neoplastic disease associated with amplification of c-erbB-2.

39. A vaccine according to Claim 38 wherein the cell membranes are derived from cells that have been transformed to overexpress c-erbB-2 or from human cancer cell lines.

40. A vaccine according to Claim 39 wherein the cell membranes are derived from recombinant hosts transformed to overexpress a form of c-erbB-2 wherein the internal domain is truncated.

41. A fused protein or polypeptide comprising a gp75 protein or polypeptide and attached thereto an amino acid sequence of a protein or polypeptide which is not immunogenic in humans and which is not typically reactive to antibodies in human body fluids.

42. A purified and isolated DNA molecule comprising the DNA sequence that codes for gp75.

43. gp75 proteins and polypeptides which are prepared synthetically.

44. A method for screening for neoplastic disease, diagnosing neoplastic disease, monitoring the disease status of patients with neoplastic disease, or prognosticating the course of

neoplastic disease comprising: detecting and quantitating the level of gp75 proteins and/or polypeptides, antibodies to gp75 protein and/or polypeptides, and ligand to c-erbB-2 correlating the detected levels; and classifying patients as to their chances of long term survival or a time to relapse of the disease.

45. A method according to Claim 44 performed after an operation to remove a tumor wherein the presence of gp75 protein/polypeptides, antibodies thereto, and/or ligand to c-erbB-2 in the human body fluid is indicative of metastases.

46. A method of treating neoplastic disease associated with the amplification of c-erbB-2 comprising the administration of a therapeutically effective amount of gp75 protein and/or polypeptide dispersed in a physiologically acceptable, nontoxic vehicle.

47. A method according to Claim 46 further comprising the administration of a therapeutically effective amount of a chemotherapeutic agent or agents in conjunction with the administration of the g75 protein and/or polypeptide.

48. A method according to Claim 47 wherein the chemotherapeutic agent or agents are alkylating agents.

49. A method according to Claim 47 wherein the chemotherapeutic agent or agents is or are selected from the group consisting of cisplatin, carboplatin and mephalan.

50. A method of treating neoplastic disease associated with the amplification of c-erbB-2 comprising the administration of a therapeutically effective amount of anti-idiotype antibodies to a monoclonal antibody to gp75 protein and/or polypeptide dispersed in a physiologicaly acceptable, nontoxic vehicle.

51. A method according to Claim 33 wherein the gp75 protein and/or polypeptide is replaced by anti-idiotype antibodies to a monoclonal antibody to gp75 protein and/or polypeptide.

52. A substantially pure glycoprotein or any portion thereof which is the ectodomain of the c-erbB-2 protein having a molecular weight of approximately 75 kilodaltons when identified on SDS-PAGE.

53. The glycoprotein of Claim 52 which has been produced by recombinant DNA methods.

54. The glycoprotein of Claim 52 which has been further glycosylated and has a molecular weight of approximately 90-kilodaltons when identified on SDS-PAGE.

55. A diagnostic method for detecting the presence of human tumor cells which overexpress the c-erbB-2 external domain glycoprotein having a molecular weight of approximately 75 kilodaltons in a human body fluid which comprises:

a) contacting the body fluid with an antibody having specificity for the glycoprotein; and

b) detecting the amount of the glycoprotein bound by the antibody, wherein an elevated level of binding above the binding level of normal cells indicates the presence of tumor cells that overexpress the c-erbB-2 external domain.

56. The method of Claim 55 wherein the antibody is a monoclonal.

57. The method of Claim 55 wherein the diagnostic method is in the form of a sandwich assay, a competition assay, a particle assay, a radiometric assay, an enzyme-linked immunosorbent assay, a radioimmunoprecipitation assay, or a fluorometric assay.

58. A method according to Claim 55 wherein the body fluid is serum, plasma, semen, breast exudate, saliva, urine or cerebrospinal fluid.

59. A method of treating a human host suspected of having cancer cells which comprises administering a therapeutically effective amount of an antibody to the c-erbB-2 ectodomain glycoprotein of approximately 75 kilodaltons.

60. Anti-idiotype antibodies to antibodies to gp75 proteins and/or polypeptides.

61. An assay to detect and quantitate ligand to c-erbB-2 in human body fluids employing gp75 proteins and/or polypeptides.

62. An assay to detect and quantitate antibodies to gp75 proteins and/or polypeptides in human body fluids employing gp75 proteins and/or polypeptides.

63. A process of purifying ligand to c-erbB-2 employing gp75 proteins and polypeptides.

64. Antibodies according to Claim 17 which are not cross-reactive with antibodies to the intact gp75 which is onthe surface of c-erbB-2 expressing cells.